

AMENDMENTS TO THE DRAWINGS

The attached Replacement Sheets of drawings include changes to Figures 1A-1B, 5A-5C and 6A-6C. These Replacement Sheets replace the original sheets which include these same Figures. In Figure 1B-6C, various handwritten numerals were corrected to be typewritten in response to the Examiner's objection to these Figures.

REMARKS

The above Amendments and these Remarks are in reply to the Office Action mailed November 15, 2006.

Currently, claims 49-104 are pending. Applicants have amended claims 89, 98 and 101-105. Applicants respectfully request reconsideration of claims 49-104.

I Objection to the Drawings

The Examiner indicated that the drawings were objected to because of lettering in Figures 1, 5 and 6. Applicant assumes that the objection was to the hand written numerals in the drawings. Figures 1B, 5A-5C and 6A-6C have been amended to change the handwritten numerals into typeface numerals. Three new drawing sheets for Figures 1A-6C with the label "REPLACEMENT SHEET" are included in this response. Applicant respectfully submits that the objection to the drawings is now moot and requests the objection be withdrawn.

II. Claim Renumbering

Examiner indicated that the numbering of the pending claims skipped claim 100, and that claims 101-105 have been renumbered as 100-104. Applicant has amended claims 101-105 to renumber them in accordance with Examiner's renumbering of the claims. Applicant will address the claims previously numbered as 101-105 as claims 100-104 for the remainder of this response to coincide with Examiner's reference to the renumbered claims.

III. Non-statutory Obvious type Double Patenting Rejection over Lo

Claims 49-51, 57-67, 75-78 and 83-88 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-17 of United States Patent No. 6843771 (*Lo*).

Applicant submits a terminal disclaimer to overcome the double patenting rejection. A rejection based on a nonstatutory type of double patenting can be avoided by filing a terminal disclaimer in the application or proceeding in which the rejection is made. *In re Vogel*, 422 F.2d 438,

164 USPQ 619 (CCPA 1970); *In re Knohl*, 386 F.2d 476, 155 USPQ 586 (CCPA 1967); and *In re Griswold*, 365 F.2d 834, 150 USPQ 804 (CCPA 1966). MPEP 804.02 (II).

Applicant is owner the present application as a result of an assignment recorded on May 6, 2006 and is owner of the *Lo* patent. The executed terminal disclaimer is filed herewith. Though Applicant respectfully disagrees that the claims are unpatentable on the ground of double patenting over *Lo*, the terminal disclaimer is submitted in order to simplify and expedite prosecution.

Because of the terminal disclaimer included herein, the double patenting rejection is now moot. Applicant respectfully submits that claims 49-51, 57-67, 75-78 and 83-88 are now in condition for allowance.

IV. Non-statutory Obvious type Double Patenting Rejection over Lo in view of Brewer or Komo or Mendlein

Claims 52-58 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 7 of *Lo* in view of any of United States Patent No. 4,847,859 (*Brewer*), United States Patent No. 5,318,035 (*Komo*) or United States Patent Publication No. 2002/0068871 (*Mendlein*).

As discussed above, Applicant herein submits a terminal disclaimer to overcome the double patenting rejection over *Lo* in view of *Brewer* or *Komo* or *Mendlein*. Though Applicant respectfully disagrees with the double patenting rejection, the terminal disclaimer is submitted in order to simplify and expedite prosecution. Thus, Applicant submits that claims 52-56 are now in condition for allowance.

V. Non-statutory Obvious type Double Patenting Rejection over Lo in view of Crutchfield

Claims 68, 89-93, 98-99 and 101-103 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over unspecified claims of *Lo* in view of United States Patent No. 6,692,443 (*Crutchfield*).

As discussed above, Applicant herein submits a terminal disclaimer to overcome the double patenting rejection over *Lo* in view of *Crutchfield*. The terminal disclaimer is submitted

in order to simplify and expedite prosecution. Applicant submits that the double patenting rejection is now moot.

Claims 89-93 are further allowable over the claims of *Lo* in view of *Crutchfield* because the cited art does not disclose the limitations recited in the claims. In addition to other patentably distinguishable elements, independent claim 89 recites in part:

an ultrasonic energy detector positioned in the module at a roof angle relative to the source of ultrasonic energy.

Neither *Lo* or *Crutchfield* disclose or suggest “an ultrasonic energy detector positioned in the module at a roof angle” as recited in claim 89. The claims of *Lo* do not disclose “an ultrasonic energy detector positioned in the module at a roof angle” as recited in claim 89. *Crutchfield* discloses a cerebral vascular health system used to monitor blood in a patients head. A probe is used to apply a signal to a patient’s skull and brain parenchyma to a blood vessel (col. 4, lines 22-26, Figures 1-4). *Crutchfield* does not disclose “an ultrasonic energy detector positioned in the module at a roof angle relative to the source of ultrasonic energy” as claimed in claim 89. Further, an ultrasonic energy detector “positioned in the module at a roof angle relative to the source of ultrasonic energy” is not obvious in view of *Lo* and *Crutchfield*, whether considered individually or together.

For at least the reasons stated above, claim 89 is patentably distinguishable over the combination of *Lo* and *Crutchfield*. Claims 90-93 are dependent on claim 89 and are thus patentable over *Lo* and *Crutchfield* as well.

Claims 101-103 are further allowable over the claims of *Lo* in view of *Crutchfield* because the cited art does not disclose the limitations recited in the claims. In addition to other patentably distinguishable elements, independent claim 101 recites in part:

an ultrasonic energy detector, the ultrasonic energy detector receives ultrasonic energy from the target blood vessel, the source of ultrasonic energy and the ultrasonic energy detector are in an angular orientation with respect to a direction of movement in said target blood vessel measured as a bias angle; and

Lo does not disclose “the source of ultrasonic energy and the ultrasonic energy detector are in an angular orientation with respect to a direction of movement in said target blood vessel” as recited in claim 101. As discussed above, *Crutchfield* also does not disclose a source of ultrasonic energy and ultrasonic energy detector “are in an angular orientation with respect to a direction of movement in said target blood vessel” as recited in claim 101.

For at least the reasons stated above, claim 101 is patentably distinguishable over the combination of *Lo* and *Crutchfield*. Claims 102-103 are dependent on claim 101 and are thus patentable over *Lo* and *Crutchfield* as well

VI. Non-statutory Obvious type Double Patenting Rejection over *Lo* in view of *Kamimoto*

Claims 69, 71-72 and 79 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over unspecified claims of *Lo* in view of United States Patent No. 6,371,920 (*Kamimoto*).

As discussed above, Applicant herein submits a terminal disclaimer to overcome the double patenting rejection over claims of *Lo* in view of *Kamimoto*. Though Applicant respectfully disagrees with the double patenting rejection, the terminal disclaimer is submitted in order to simplify and expedite prosecution. Applicant submits that claims 69, 71-72 and 79 are now in condition for allowance, and that the double patenting rejection over *Lo* in view of *Kamimoto* is now moot.

VII. Non-statutory Obvious type Double Patenting Rejection over *Lo* in view of *Nakamura*

Claims 70, 73-74 and 79 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over unspecified claims of *Lo* in view of United States Patent No. 6,554,772 (*Nakamura*).

Applicant herein submits a terminal disclaimer to overcome the double patenting rejection over claims of *Lo* in view of *Nakamura*. Though Applicant respectfully disagrees with the double patenting rejection, the terminal disclaimer is submitted in order to simplify and expedite

prosecution. Applicant submits that claims 70, 73-74 and 79 are now in condition for allowance, and that the double patenting rejection over *Lo* in view of *Nakamura* is now moot.

VIII. Non-statutory Obvious type Double Patenting Rejection over Lo in view of Durley

Claims 80-82 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over unspecified claims of *Lo* in view of United States Patent No. 4,413,629 (*Durley*).

Applicant herein submits a terminal disclaimer to overcome the double patenting rejection over claims of *Lo* in view of *Durley*. Applicant respectfully disagrees with the double patenting rejection but submits the terminal disclaimer in order to simplify and expedite prosecution. Applicant submits that claims 80-82 are now in condition for allowance, and that the double patenting rejection over *Lo* in view of *Durley* is now moot.

IX. Non-statutory Obvious type Double Patenting Rejection over Lo in view of Crutchfield and Yamimoto

Claim 94 is rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over unspecified claims of *Lo* in view of *Yamimoto*.

Applicant herein submits a terminal disclaimer to overcome the double patenting rejection over claims of *Lo* in view of *Yamimoto*. Applicant respectfully disagrees with the double patenting rejection but submits the terminal disclaimer in order to simplify and expedite prosecution. Applicant submits that claim 94 is now in condition for allowance, and that the double patenting rejection over *Lo* in view of *Durley* is now moot.

X. Non-statutory Obvious type Double Patenting Rejection over Lo in view of Crutchfield and Nakamura

Claims 95-97, 100 and 104 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over unspecified claims of *Lo* in view of *Crutchfield* and *Nakamura*.

Applicant herein submits a terminal disclaimer to overcome the double patenting rejection over claims of *Lo* in view of *Crutchfield* and *Nakamura*. Applicant respectfully disagrees with the double patenting rejection but submits the terminal disclaimer in order to simplify and expedite prosecution. Applicant submits that claims 95-97, 100 and 104 are now in condition for allowance, and that the double patenting rejection over *Lo* in view of *Crutchfield* and *Nakamura* is now moot.

XI. Rejection under 35 USC 103

The Examiner rejected claims 89-104 under 35 USC 103(a) as being unpatentable over the combined teachings of *Nakamura*, *Crutchfield* and *Kamimoto*.

Claim 89-97

The claimed embodiment of claim 89 is patentable over the combined teachings of *Nakamura*, *Crutchfield* and *Kamimoto*. Select features of embodiments of Applicant's invention as described above can be found in claim 89 which recites among other limitations:

at least one source of ultrasonic energy located in a module, the source emitting ultrasonic energy of an operating frequency of 2 MHz or lower;
a gel pad displaced between the at least one source of ultrasonic energy and the ultrasonic energy detector and the living subject.
wherein the ultrasonic monitor is worn on the wrist of the living subject being monitored.

The combination of *Nakamura*, *Crutchfield* and *Kamimoto* does not disclose or suggest the limitations of claim 89. *Nakamura* discloses a pulse wave detection device. The device includes an acoustic matching layer 48 disposed between the piezoelectric elements and an organism being monitored (col. 5, lines 33-34). The acoustic matching layer is a flat layer, resulting in the piezoelectric elements positioned directly parallel with respect to each other and towards the subject (Figures 3, 10-16). *Nakamura* does not disclose "a gel pad" within the pulse wave detection device. Rather, *Nakamura* discloses a flat, acoustic matching layer.

Crutchfield discloses a cerebral vascular health system used to monitor blood in a patient's head. A probe is used to apply a signal to a patient's skull and brain parenchyma to a

blood vessel (col. 4, lines 22-26, Figures 1-4). *Crutchfield* includes a system that may communicate with a web server 2330, email server (Figure 23) and includes a video screen, a GUI 1030 for receiving input, and a printer (col. 23, lines 35-40; col. 32, lines 50-60, Figure 10; col. 34, lines 29-32).

Crutchfield does not disclose or suggest “a gel pad displaced between the at least one source of ultrasonic energy and the ultrasonic energy detector” as recited in claim 89. Rather, *Crutchfield* discloses that a *probe* is manually placed against a subject’s head by an operator (Figures 1-4). *Crutchfield* does not disclose an ultrasonic monitor that can be “worn on the wrist of a subject being monitored” as recited in claim 89. *Crutchfield* is used to measure information within a subject’s skull rather than a subject’s wrist. Also, the system of *Crutchfield*, which includes a video screen and a printer, would not be appropriate as a wrist worn device.

Kamimoto discloses a pulse wave detecting device having a plurality of sets of piezoelectric vibrators. The piezoelectric vibrators transmit an ultrasonic wave toward an artery and receive ultrasonic waves propagating through the artery (col. 2, lines 20-25). The piezoelectric vibrators are positioned in a V-formed groove (col. 8, lines 59-67, Figures 4B-C). There is no indication of the range formed by the v-formed groove of the piezoelectric elements of *Kamimoto*. The piezoelectric vibrators are positioned against the skin of the subject (Figures 4A-5A).

Kamimoto does not disclose “a gel pad displaced between the at least one source of ultrasonic energy and the ultrasonic energy detector” as recited in claim 89. Rather, piezoelectric vibrators positioned in a V-formed groove are placed directly in contact with a subject’s skin. *Kamimoto* does not disclose “a gel pad” or that any element is placed between “between the at least one source of ultrasonic energy and the ultrasonic energy detector” as recited in the claimed embodiment of claim 89.

The combined teachings of *Nakamura*, *Crutchfield* and *Kamimoto* do not disclose claim 89. In particular, the cited references do not combine to teach or suggest “a gel pad displaced between the at least one source of ultrasonic energy and the ultrasonic energy detector” as recited in claim 89. *Kamimoto* actually teaches away from a gel pad because the piezoelectric

vibrators are placed directly against the skin of a subject. None of the references suggest the use of a “gel pad” between piezoelectric elements and a subject.

Furthermore, *Crutchfield* should not be combined with *Nakamura* and *Kamimoto* because it is not related with these references. *Crutchfield* is a large scale system used to measure brain information using a probe applied to the head of a patient. *Nakamura* and *Kamimoto* disclose small, portable wrist worn devices. *Crutchfield* is not used as a wrist worn device. Rather, *Crutchfield* teaches away from a portable wrist worn system because of the elements *Crutchfield* includes, such as a video screen that provides a GUI interface and a printer. For at least these reason, *Crutchfield* one of ordinary skill in the art would not be motivated to combine teachings of *Crutchfield* with *Nakamura* and *Kamimoto*.

Because the combination of *Nakamura*, *Crutchfield* and *Kamimoto* fail to disclose of suggest each limitation of claim 89, Applicant asserts that claim 89 is patentable over the cited art. Claims 90-97 each ultimately depend from claim 89 and should be patentable for at least the same reasons in addition to the distinguishable elements they recite.

Claim 97 is further patentable over the cited art. Claim 97 includes the limitation of “the first and second piezoelectric crystals are positioned from an artery of the subject by a distance of between about 3-10 mm.” The cited references do not disclose or suggest, either individually or combined, that piezoelectric crystals are positioned from an artery within the range recited in claim 97.

Claim 98-100

The claimed embodiment of claim 98 is patentable over the combined teachings of *Nakamura*, *Crutchfield* and *Kamimoto*. Select features of embodiments of Applicant’s invention as described above can be found in claim 98 which recites among other limitations:

providing an ultrasonic monitor, the ultrasonic monitor comprises at least one source of ultrasonic energy having an operating frequency of 2 MHz or lower, an ultrasonic energy detector, a gel pad and associated hardware and software for detecting, calculating and displaying a readout of the measured rate values

As discussed above with respect to claim 89, the combination of *Nakamura*, *Crutchfield* and *Kamimoto* does not disclose a heart rate monitor which includes a gel pad. The limitation of “a gel pad” is recited in claim 98. Because the combination of *Nakamura*, *Crutchfield* and *Kamimoto* fail to disclose of suggest each limitation of claim 98, Applicant asserts that claim 98 is patentable over the cited art. Claims 99-100 each ultimately depend from claim 98 and should be patentable for at least the same reasons in addition to the distinguishable elements they recite.

Claim 101-104

The claimed embodiment of claim 101 is patentable over the combined teachings of *Nakamura*, *Crutchfield* and *Kamimoto*. Select features of embodiments of Applicant’s invention as described above can be found in claim 101 which recites among other limitations:

a gel pad displaced between the source of ultrasonic energy and the ultrasonic energy detector and the living subject.

As discussed above with respect to claim 89, the combination of *Nakamura*, *Crutchfield* and *Kamimoto* does not disclose a heart rate monitor which includes a gel pad. The limitation of “a gel pad” is recited in claim 101. Because the combination of *Nakamura*, *Crutchfield* and *Kamimoto* fail to disclose of suggest each limitation of claim 101, Applicant asserts that claim 101 is patentable over the cited art. Claims 101-104 each ultimately depend from claim 101 and should be patentable for at least the same reasons in addition to the distinguishable elements they recite.

Conclusion

Based on the above amendments and these remarks, reconsideration of claims 49-104 is respectfully requested.

The Examiner's prompt attention to this matter is greatly appreciated. Should further questions remain, the Examiner is invited to contact the undersigned attorney by telephone.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 501826 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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